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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1301	8

DATE MAILED: [illegible]/21/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 10/21/96.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 21-39 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 21-25, 27-30, 34-35 is/are allowed.

☒ Claim(s) 26, 31-33, 36-39 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 substitute

☐ Notice of Informal Patent Application, PTO-152

– SEE FFICE ACTION ON THE FOLLOWING PAGES –

* U.S. GPO: 1996-410-238/40059

Part III DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-10, drawn to polynucleotides and methods of making proteins, classified in Classes 536 and 435, subclasses 23.1 and 69.1, respectively, for example.

Group II. Claim 11, drawn to a polypeptide, classified in Class 530, subclass 399, for example.

Group III. Claim 12, drawn to an agonist, classified in Class 530, subclass 300, for example, but this will vary depending on the nature of the agonist.

Group IV. Claim 13, drawn to an antagonist, classified in Class 530, subclass 300, for example, but this will vary depending on the nature of the antagonist.

Group V. Claim 14, drawn to a method of treating using a polypeptide, classified in Class 514, subclass 12, for example.

Group VI. Claim 15, drawn to a method of gene therapy, classified in Class 514, subclass 44, for example.

Group VII. Claim 16, drawn to methods of treating using an agonist, classified in Class 514, subclass 2, for example, but this will vary depending on the nature of the agonist.

Group VIII. Claim 17, drawn to methods of treating using an antagonist, classified in Class 514, subclass 2, for example, but this will vary depending on the nature of the antagonist.

Group IX. Claim 18, drawn to a method for detecting mutations, classified in Class 536, subclass 24.31, for example.

Group X. Claim 19, drawn to a method for detecting a polypeptide, classified in Class 436, subclass 501, for example.

Group XI. Claim 20, drawn to a method of identifying compounds, classified in Class 435, subclass 7.1, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the polypeptide of Group II could be made by an entirely different method (such as synthetically) rather than by the method of Group I.

3. Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the DNA of Group I could be used in a method of hybridization rather than in the method of therapy of Group II.

4. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptide of group II could be used in an entirely different process, such as in the production of antibodies, rather than in the method of Group V.

5. Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the method of Group VII could be practiced with an entirely different compound, such as with the polypeptide itself, rather than with the agonist of Group III.

6. Inventions IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the antagonists of Group IV could be used in a method of making antibodies rather than in the method of Group VIII.

Inventions I and II are related as polynucleotides encoding the polypeptide and the polypeptide. Inventions I and III-IV are related as polynucleotides encoding the polypeptide and agonists or antagonists to the polypeptide, respectively. Inventions I and (V, VII-XI) are not related because the polynucleotides of Invention I are not necessary for any of the methods of Groups V and VII-XI. Inventions II and III-IV are related as the polypeptide and agonist or antagonists of the polypeptide, respectively. Inventions II and VI-XI are not related because the polypeptide of Group II is not necessary to practice any of the methods of Groups VI-XI. Inventions III and VI are related as agonists and antagonists to the polypeptide. Inventions III and (V-VI, VIII-XI) are not related because the agonist of Group III is not necessary to

practice any of the methods of Groups V-VI, VIII-XI. Inventions IV and (V-VII, IX-XI) are not related because the antagonist of Group IV is not necessary for the practice of any of the methods of Groups (V-VII, IX-XI). Inventions V-XI are not related because they are all directed to methods which are not related to one another, are distinct, and are not required one for the other.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the reasons given above and below.

Groups I-IV are directed to products that are distinct both physically and functionally and are, therefore, patentably distinct; and are not required one for the other. Furthermore, the protein can be made by materially different processes such as chemical synthesis. The polynucleotides can be used other than to make the protein and neither the protein or the polynucleotides are necessary for the production of agonists or antagonists, or vice versa.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the reasons given above.

The inventions of each named pair can be shown to be distinct because they do not rely upon each other for their ultimate use and they require non-coextensive literature searches. The compounds are physically and functionally distinct and are not required one for the other and the methods have different goals, method steps, and/or starting materials.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

7. A telephone call was made to J. G. Mullins (Reg. # 33,073) on August 1, 1996 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicants specifically requested a written restriction for their convenience.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 4PM.

The fax phone number for this Group is (703) 308-0294. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christine Saoud, Ph.D.
August 5, 1996
cs

JOHN ULM
PRIMARY EXAMINER
GROUP 1800

Attachment 8

The drawings submitted with this application were declared informal by the applicant. Accordingly, they have not been reviewed by a draftsperson at this time. When formal drawings are submitted, the draftsperson will perform a review.

Direct any inquiries concerning drawing review to the Drawing Review Branch (703) 305-8404.